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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Paul V. Goode JR.

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06/23/2009

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EXAMINER

JANG, CHRISTIAN YONGKYUN

ART UNIT

PAPER NUMBER

3735

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/648,849	Applicant(s) GOODE ET AL.	
	Examiner CHRISTIAN Y. JANG	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 118-126 and 148-161 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 118, 123-126 and 148-161 is/are rejected.
- 7) ☒ Claim(s) 119-122 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/6/05, 3/9/27, 7/3/07, 10/2/07, 9/4/08, 1/12/09, 5/19/09</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to communications filed March 17th, 2009.

Claims 118-126 and 148-161 are pending in the instant application.

Information Disclosure Statement

2. The IDS submitted on June 6th, 2005, March 9th, 2007, July 3rd, 2007, October 2nd, 2007, September 4th, 2008, January 12th, 2009, and May 19th, 2009 have been considered in full by the examiner.

3. Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. See MPEP 609.05(b). Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 160 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 160 recites a step of detecting transient non-

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glucose related signal artifact performed on the calibrated data stream. The specification fails to provide support for such a feature.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 161 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. As to claim 161, the metes and bounds of the phrase “physiologically feasibility” are unclear, and the specification does not provide sufficient support for what such a phrase means.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 118, 123-126, 148-155, 158 and 159 are rejected under 35 U.S.C. 102(b) as being anticipated by Parris et al. (US 2002/0026110).

11. As to claim 118, Parris teaches a method for processing data from a glucose sensor, comprising monitoring a data stream from a glucose sensor (Abs), detecting transient non-glucose related signals and evaluating a severity of the artifact and replacing at least some of the signal values with one or more estimated glucose values ([0239-0243]).

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12. As to claim 123, Parris teaches the application of one of a plurality of signal estimation algorithm factors in response to the severity of the signal artifacts (Fig. 13).

13. As to claim 124, Parris teaches the application of a single algorithm with a plurality of parameters that are selectively applied to the algorithm (Fig. 13; several models use a plurality of parameters).

14. As to claim 125, Parris teaches a plurality of distinct algorithms (Fig. 13).

15. As to claim 126, Parris teaches the selective application of a predetermined algorithm that comprises a set of parameters whose values depend on the severity of the signal artifacts ([0248]).

16. As to claim 148, Parris teaches replacing signal artifacts comprises outputting data representative of one or more of the estimated glucose values including a numeric representation ([0243]).

17. As to claim 149, Parris teaches the use of filtered data streams when the signal artifacts meet one or more predetermined criteria. ([0176-0177] - the use of the predictive kinetic method is capable of being used during error causing physiological phenomena such as temperature).

18. As to claim 150, Parris teaches the use of an unfiltered data stream when the signal artifacts do not meet one or more predetermined criteria (claim 1).

19. As to claim 151, Parris teaches data stream monitoring comprises receiving data from one of a non-invasive, minimally invasive, or an invasive glucose sensor (Fig. 1).

20. As to claim 152, Parris teaches an enzymatic glucose sensor ([0003]).

21. As to claim 153, Parris teaches the monitoring of a pH ([0171]).

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- 22. As to claim 154, Parris teaches the use of linear regression ([0124]).
- 23. As to claim 155, Parris teaches continual correction ([0072]).
- 24. As to claim 158, Parris teaches the discarding of signal artifacts (error correction inherently throws out the signal artifacts).
- 25. As to claim 159, Parris teaches the calibration of the data stream ([0010]).

Claim Rejections - 35 USC § 103

26. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 27. Claims 156 and 157 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parris et al. (US 2002/0026110).
- 28. As to claims 156 and 157, Parris does not explicitly state the initiation of an artifacts replacement step when the artifacts meet one or more predetermined data and the termination of the step if it does not. However, it would have been obvious to one of ordinary skill in the art to initiate error correction when artifacts are detected. As such, it would have been obvious to one of ordinary skill in the art to modify the method of processing sensor data as taught by Parris to be utilized in the event an artifact is detected.
- 29. Claim 160 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parris et al. (US 2002/0026110) in view of Goode, JR. et al.

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30. As to claim 160, Parris does not teach the step of detecting non-glucose related artifacts to be performed on the calibrated data stream. However, Goode teaches an analyte sensor with an initial calibration and re-calibration of the sensor. As such, it would have been obvious to one of ordinary skill in the art to modify the method for processing data taught by Parris to further process the removal of signal artifacts on a pre-calibrated data stream.

Allowable Subject Matter

31. Claims 119-122 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

32. As to claim 119-122, the prior art of record fails to teach or fairly suggest a method, as claimed by Applicant, wherein the severity evaluation is based on an amplitude, duration, rate-of-change, or a frequency content of the transient non-glucose related signal artifact.

33. Claim 161 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

34. As to claim 161, the prior art of record fails to teach method as claimed by Applicant including a signal artifacts replacement step comprising the measurement of at least one of rate of change, acceleration, and physiologically feasibility of one or more calibrated glucose values.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN Y. JANG whose telephone number is (571)270-3820. The examiner can normally be reached on Mon. - Fri. (8AM-5PM) EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

CJ
/C. Y. J./
Examiner, Art Unit 3735
6/17/09

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